Usability Testing and the Relation of Clinical Information Systems to Patient Safety

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Abstract

Background: The success of clinical information systems depends upon their effective integration into complex work systems involving distributed responsibility and decisionmaking. Human-computer interaction (HCI) deficiencies and mismatches between systems design and the structure of work create the potential for new paths to system failures (e.g., allergy lists not directly visible on a screen). The use of human factors methods is widespread in other industries and can predict some of these new failure paths, facilitating redesign to prevent accidents-in-the-making. This paper will discuss the application of scenario-based usability testing in clinical health care settings. **Methods:** Using scenario-based usability testing methods, we investigated point-of-care software technology (e.g., barcoded medication administration [BCMA] and wireless medication administration [WMA]) in an attempt to better understand the safety implications of HCI design decisions. The use of scenarios in usability testing focuses attention on specific aspects of the interface to identify pitfalls and system failures. The scenarios were developed after extensive ethnographic observation of the medical work with bar-coding software and the computerized order entry system (COES). **Results:** The paper lays out the methodology of scenario-based usability testing for use in health care. We were able to identify new paths to failures using this method and recommended the software to simplify and support the user's tasks. Scenario-based testing also identified workplace performance trade-offs related to time and production pressures. **Conclusion:** Scenario-based usability testing is an important methodology that characterizes how human-software interaction contributes to success or failure in clinical system implementations. Usability testing can identify and promote data-driven design choices culled from practitioner use of the system in a busy work environment. Human factors knowledge of HCI design and its impact on human performance can advance safety in health care.

Introduction

In health care, as in other domains, the expectations surrounding new and as-yet-unproven technologies often are far more optimistic than is reasonable. These new technologies often are sold on the basis of their presumed positive human performance impacts. For example, clinical information systems have been advocated to reduce the risk of adverse drug events at each stage in the medication administration process.[1] These systems, including computerized physician order entry (CPOE), automated dispensing systems, and barcode

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technology, achieve this new level of "safety" through reduced reliance on memory, increased access to information, and increased compliance with "best practice" procedures.[2]

But in addition to providing new capabilities, new technologies also impact the technical, social, organizational, economic, cultural, and political dimensions of work in new and different ways.[3] Observations of new technology implementations have shown that a change in technology literally alters roles, strategies, and paths to failure.[4] In recognizing this, the Institute of Medicine report, *To Err Is Human,* recommends examining new technologies for "threats to safety and redesign(ing) them before accidents occur."[5] In order to minimize harm, we propose to anticipate the side effects of introducing clinical information systems in work practice, using proactive testing methods.

This paper describes a method of scenario-based usability testing and its usefulness in identifying negative, unanticipated side effects in a clinical information system. The main advantage of this approach is its ability to identify impact prior to implementation and to suggest redesign before adverse events or injury to patients can occur. The testing results reveal unintended side effects from design decisions based on oversimplified models of the work. Analysts can use the observations to suggest critical elements of work processes for maximal or "best" performance with the information system, while generating ideas for system redesign in the long term.

Background

Usability testing

Software applications in the computer industry routinely undergo some type of formal usability testing. This evaluation proves important, particularly in complex sociotechnical systems where work is distributed across time and space, and multiple tasks continuously compete for the attention of the worker. Other high-consequence industries, such as nuclear power and aviation, are similar to health care in terms of their safety standards and the need to maintain a high level of reliability. In each of the fields, the role and impact of the information system is heightened because of the immediate effect on human lives. A difficult-to-use interface in clinical settings not only will impact profit and productivity, but also patient safety. Design of clinical information systems should ideally simplify work processes, resulting in improved efficiency and increased safety. Given finite time constraints, the most important relationship of efficiency to safety becomes obvious. If performance and individual tasks are slowed, then less time or attention is available for the work tasks, promoting mental slips and predictable human adaptations to workload (e.g., shed tasks, decreased performance criteria, and differing tasks—all generally described as "cutting corners").[6, 7]

The traditional usability test involves observations of workers completing tasks with the use of the computer interface.[8] Usability as a construct has multiple components: learnability, efficiency of use, ease of recall, low error generation,

and subjective pleasure.[8] Health care brings its own constraints to tool design. The distributed nature of the work requires accurate access to information. The pace and tradition in health care limits access to consistent training, which in turn increases the importance of learnability and ease of use.

The usability test can be a conducted using a variety of methodologies (e.g., thinking-aloud, constructive interaction, retrospective testing, and coaching). The most popular method is "thinking-aloud,"[9] in which users verbalize their thoughts while using the device interface. The process of thinking aloud allows analysts to better understand the mental model employed by the users, as well as the particular aspects of the interface that cause the most problems. The literature regarding human-computer interaction suggests that usability testing by three to five users appears to find about 85 percent of major interface usability problems.[10] Identification of serious usability problems in advance of the software release improves performance and acceptance of the software. Most usability tests are videotaped to permit analysis of statements of confusion and errors in using the system.

Scenario-based testing

Usability testing embedded in a scenario allows the simulation to be grounded in the observation of the work practice context. Most interface testing is designed to complete the simple, straightforward task. Difficulty in design decisions can more easily be created when "typical" work with its time pressure, competition for attention, and interruptions. Grounding the testing in the work is necessary, because complexity reveals latent software problems of the sort that simple, straightforward repetition often does not reveal. The design of a scenario replicates the use of a system, the user's interaction with it, and the performance of an activity over a specified period of time. These testing methods provide opportunities for learning how the system actually functions and malfunctions, through demonstrations of how practitioners accommodate and adapt to the technology change, without causing patients actual harm. The clinical information system also is observed in testing to determine how the technology transforms roles, coordination, and the means by which people adapt to the mix of new capabilities and complexities. This information helps to reveal the organizational, design, and training adjustments necessary to make the system more useful, while reducing unintended side effects related to the change.

Ethnographic observations and structured interviews associated with scenario design

In an attempt to develop an accurate and representative scenario of the work practice, an intimate picture of how the work is accomplished is created using ethnographic observations from trained observers. Ethnographic observations[12] and structured interviews are conducted in the workplace prior to the scenario design activities to better understand key aspects of work, particularly those areas involving communication, collaboration, expertise, in-place safeguards, competing tasks, interruptions, etc. The observations and interviews facilitate

development of a predicted-use model and its positioning in a workplace context. This framework then is used to develop scenario-based usability tests modeled on the interface features in a typical sequence of events and targeted situations, to test issues identified during the observations. The analyst then can use the scenario design to predict use and sources of difficulty.

To conduct the aforementioned ethnographic observations, trained observers captured detailed data, including (1) observable activities and verbalizations, and (2) subject-reported data about how artifacts (tools) support performance.[11] The observer also captured the sequence of events as well as other details of the communication, interactions, and teamwork of the clinician user. Because the information was gathered prospectively, the data quality was high and was judged to be representative of "typical" behavior, as opposed to retrospective or generalized subject-reported behavior obtained through an interview. The risk of behavior modification associated with the observation process itself was minimized through the use of a pilot phase, prior to data collection, and by asking the trusted practitioners to judge whether or not they acted in a typical fashion. The results of the analysis provided the areas of concentration necessary for development of the scenarios and the usability testing. The data collected from multiple workers then was studied for themes, patterns, strategies, and tools used to complete the task. Reliability and validity was derived using the triangulation of findings from multiple individuals and multiple data sources.

Structured interviews were used in conjunction with (or in place of) ethnographic observations during data collection to get a more complete understanding of work processes. When researchers observe ambiguous or complex actions, it is important to conduct such questioning to elucidate their meaning. Data collection through structured interviews is replicable in that the same questions are asked with the same words in every interview. Although it is believed that some aspects of expertise—particularly processes involving physical movement—are incapable of being self-reported, it is considered valid to use self-reporting techniques to elicit "textbook" knowledge such as the typical workflow of surgical procedures. Data analysis involves compiling transcribed responses from de-identified interviewees for each question, then synthesizing those views central to the majority of the participants and characterizing the variability in perspectives among those interviewed.

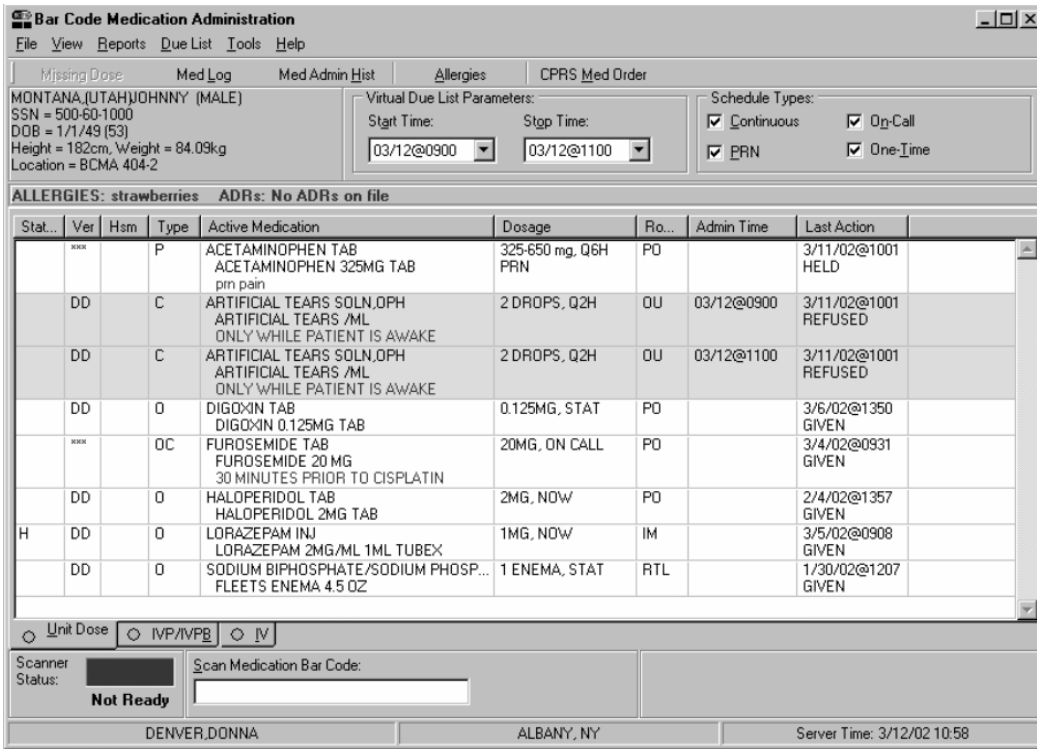
Methods

The entire scenario-based usability testing process is composed of four major steps: (1) data collection for the work to be studied (e.g., ethnographic observations, structured interviews), (2) scenario development, (3) scenario-based user testing, and (4) data analysis. In this section we describe each step, followed by a case study.

Setting

The Veterans Health Administration (VHA), one of the largest health care systems in the United States, is a leader in the use of medical informatics systems. In 1997, the VHA implemented computerized patient record system (CPRS),[13] which is integrated with the Veterans Health Information Systems and Technology (VistA) database.[14] The VistA database is a collection of tools that permit interfacility networking, data sharing, and specialized central support.[14] A graphical user interface (GUI) for CPRS was later developed and implemented to replace the original command line interface. In 2000, the VHA implemented the barcoded medication administration (BCMA) system, which uses scanned barcodes to ensure that each patient gets the correct medication in the correct dose and route, at the correct time. Figure 1 is a list of medications for one particular patient and the order in which they are to be given—the "due list." BCMA has been deployed in all VHA facilities across the United States.

Figure 1. A virtual BCMA due list (version 2.0)



A corporation outside of the VHA introduced the use of wireless medication assistants (WMAs) with built-in barcode scanners to support medication administration. Both the patient's hospital wristband and his or her medication labels are barcoded for the patient's safety. The WMA application was developed to emulate an existing BCMA desktop application. The WMA software is loaded on a personal digital assistant (PDA), specifically the Symbol Technologies® Model PPT 2800, with a 206 MHz processor, running the Microsoft® Pocket PC 2002 operating system. The WMA system was used briefly by a small number of

VHA facilities prior to the start of the evaluation process, but a moratorium was placed on the use of the system in the field until the evaluation was completed. The system has since been cleared for use.

Step 1—Ethnographic observations

The scenarios used for testing are designed using problems derived from observations of the work environment in which the software was to be used.

BCMA example

Nurses accessed the BCMA software using a laptop computer fixed to a wheeled medication cart and linked to the VHA's electronic databases via a wireless network. The nurse scanned the barcode on the patient's wristband to select that individual's medication regimen from the database and present it on the computer's display. Each medication container barcode then was scanned to verify that the medication, dose, route, and administration time match what was ordered by the patient's physician. If the drug formulation information associated with the barcode matched the displayed database information, the system then noted the medication was administered by the nurse at the time the wristband was scanned. If the scanned information associated with the medication did not match the patient's medication orders, a pop-up dialog box appeared on the laptop computer screen to alert the nurse to the discrepancy.

Medication administration was observed in the acute care and nursing home wards of three VHA hospitals. Three observers trained to perform ethnographic observations in complex settings conducted all observations. To minimize the effect of the observations on the behavior of the study participants, no data that could identify person, place, or time of day was collected, nor was any demographic information or medication error rate information recorded. We observed nurses using BCMA equipment at one small, one medium, and one large hospital facility for periods ranging from 24 to 31 hours, for a total of 79 hours. Patterson and colleagues[15] reported the observations specifics and their conclusions in a prior publication. These observations were used to direct the development of scenarios for use in the testing of BCMA.

Unlike BCMA, ethnographic observations of hospital staff using the WMA system were not possible, given that it was not in use in any of the studied facilities. To replicate the data retrieved from this process, structured interviews were instead used to assist in the development of a predicted use model and to identify potential sources of error. One researcher conducted structured interviews with nurses at two hospitals who had used the WMA system briefly.

Step 2—Scenario development

The first step in developing a scenario is identifying the most problematic areas of work (e.g., as a result of the analysis of the observations) and creating probes of specific elements in the medication administration process that will require the use of decisionmaking principles in context. In addition to

observations, a good source of probes is the stories related by workers about the difficulties of the system implementation. Probes are best developed through a partnership involving human performance expertise and clinical expertise.

The next step in the scenario development process is identifying constraints in terms of the work volume, time frame, task complexity, and contextual factors. To the extent possible, complete cases are constructed with laboratory values, radiology results, progress notes, prior medication records, and discharge summaries. This initial effort creates a catalogue of cases with which additional testing for difficult functionality is possible. Access to electronic medical records in a de-identified test account, as well as an extensive clinical expert, facilitates the process.

BCMA example

The scenario used to test BCMA took the form of a "shift change" report and involved administering medication to a number of simulated patients with barcoded wristbands. To imitate the usual/minimal amount of patient-specific knowledge, part of the testing involved listening to a taped "shift change" report. We created a model of a busy 9 a.m. medication distribution pass, usually with four to six different patients. The test subject (nurse) then chose the order in which the patients would be medicated and began the exercise. Simulated barcodes for patients, medications, and a medication cart were provided to support the testing. Because interruptions are common in nursing work, some were also built into the scenario. As an example, here is the transcript of the shift change report for one of the hypothetical test patients:

> *Mr. A is an elderly 60 kg BM with a past medical history significant for severe COPD FEV1 300 cc., and CHF with EF of 20% who presents to ED with 3 days of increased shortness of breath associated with green sputum, PND and orthopnea, and increased LE swelling. He was admitted last night to the ICU. He is visibly anxious with a RR of 40 and ABG 7.31/55/55 on 35% venti mask. CXR remarkable for infiltrate in both bases thought secondary to congestive heart failure. BP is 110/60, P 120, T 100, O2 sat 88% on 40%. The patient has one peripheral IV and a triple lumen in his right subclavian. In the triple lumen, one port has theophylline, another port is for the IV meds.*

Sample interruptions in the exercise included the following:

- Ringing telephone (the nurse answered it and heard the following reply): "This is the lab, can I talk to the nurse caring for Mr. Smith? Hi, we have two critical results on Mr. Smith, XXX-XX-XXXX. In the arterial blood gas, pH of 7.29, PaO_2 of 60, and a $PaCO_2$ of 60, and the potassium is 2.9."
- At one point a nurse manager asked the test subject, "Can you work an extra shift?"

- An alarm for bradycardia was triggered in another room.
- The wife of "Patient #1" told the nurse, "He wants a drink of water!"
- An individual imitating a physician approached and asked the nurse, "Are you the nurse for Mr. X? Lab just called me… Mr. X's Creatinine is 2.6, how much digoxin has he gotten?"

WMA example

Scenario development for WMA testing was adjusted from the BCMA example to better explore how the small screen on the PDA affected access to important data (e.g., patient identifiers, allergy information, medication administration history, etc.). The following is an excerpt from the shift change report transcript for one of the hypothetical test patients:

> *Room 45 - Bed 2, Mr. X is a 90-kg BM with a past medical history significant for diabetes. Was admitted to the VA 4 times in this year, underwent Fem-pop bypass left. Has a left second and third toe amputation and has a decub ulcer too. He was admitted last night to the ward. BP is 132/60, P 98, T 97. The patient has one peripheral IV and a triple lumen in his right subclavian. In the triple lumen, one port has theophylline, another port is for the IV meds.*

This scenario is slightly different than the BCMA example in that it was designed to test the impact of the WMA screen design on the display of patient identifiers and medication administration history.

Step 3—User testing

As outlined in the background section, usability testing is a method for examining the interaction between the user and the computer interface. Part of the testing plan includes determining the appropriate number of practitioners to be tested and the level of expertise needed in the test subjects. Generally, tests include both novice and expert users. Subjects are solicited from the hospital staff through advertisements (posters, etc.) displayed in relevant work units. To prevent a potential conflict of interest, the testing must be scheduled for a time when the participants were not being paid by the hospital. The subject selection is determined by the order in which they volunteered, and the advertisements should state the duration of the tests, the expectations, the fact that video and audio taping may be involved, and the specific functionalities to be tested. Such testing often must be cleared by union and hospital leadership.

A pilot test often is conducted, due to the complexity of the information system set up and the clinical topics covered. The pilot test verifies that the cases are available in the dataset, the barcodes are correct, and the interface is operable from the testing location, while at the same time helping those running the test to create a smooth, consistent testing environment. Pilot subjects are usually tested

at least 24 hours prior to the actual tests, and the data collected during the pilot testing is not usually included in the data analysis.

We have found that having two testers present during the exercise is helpful—one to interact with the nurse subject (i.e., to introduce the interruptions), while the other collects data (e.g., taking notes and reminding the test subject to verbalize their thoughts as they work their way through the exercise). A debrief interview is conducted following the test to obtain further information from the test subject on their opinion of the interface and the confusion and difficulties they experienced with the software. An industrywide usability questionnaire[16] allows the test subject to articulate their level of satisfaction with the interface and its impact on their work. The actual testing process includes—

- Written introduction to the testing process
- Introduction to the scenario, e.g., listening to the "shift change report"
- Complete simulation, e.g., pass barcoded medications to simulated patients with barcoded wristbands, frequent interruption by phone and in person during medication pass, verbalizing what they were thinking during the test—"thinking aloud"
- Debrief interview following test and satisfaction questionnaire

Great care should be taken to ensure that all testing is done in a well-identified test account, so that the data can be manipulated without affecting that of real hospital patients. Data in the test account must be representative of the data that is available to practitioners in the live patient account for the simulation to be successful.

BCMA example

Usability testing for Version 1 of BCMA involved five nurse subjects, each participating for 90–120 minutes. Additional testing was done on subsequent versions with the same number of participants. Each test involved an identical agenda:

- Each study participant was scheduled and paid for two hours of their time.
- The purpose of the study was described to each participant during the testing session, informed consent forms for video and audio taping were signed, the participants practiced "thinking aloud" with standard practice examples (e.g., multiply 24 times 34), after which a taped "shift change" report was played and/or read (a standard practice during shift changes on acute care wards in VHA hospitals).
- The participant was then instructed to play the shift change update, which could be played multiple times, while taking notes.
- The participant was provided with a medication cart, featuring an attached laptop computer and barcode scanner identical to that used on

the patients wards. Barcoded wristbands and empty medication packages with appropriate barcodes were provided for the purpose of scanning and simulating the administration of the medication.

- The participants were required to answer the telephone and provide simulated responses to requests from testers who interrupted their procedural work.
- At the end of the session, a debriefing interview was conducted to better identify and understand activities that occurred during the simulation, and a short usability questionnaire[16] was completed.

WMA example

The usability testing for the WMA device involved a total of five subjects (with one used to pilot test the scenarios and the testing process as it was tailored for this system), each participating for 90–120 minutes. A program patch had been installed to eliminate unexpected side effects, just prior to the time the usability testing originally was to have been conducted. But the patch altered the usability of the orders that should have appeared on the IV page tab (they were missing), which forced the rescheduling of the test and further reinforced the importance of a pilot run.

Step 4—Data analysis

Following the user testing, the analysts list the common sources of interface difficulty experienced by the users. The videotape of the testing session then is reviewed, the patterns of use are counted, and notes are made on the evidence of adaptation to work constraints (e.g., deferring tasks, shedding tasks, decreasing performance, etc.) and the perceived need for artifacts. The user actions and verbalizations are analyzed for confusion and difficulties related to meeting task goals, and time spent on tasks. The created list of interface problems then is prioritized on the basis of risk to patients and ease of improvement (i.e., low hanging fruit, critical, moderate, and long-term change). This analysis is done to advance a dialogue with the designers on the best methods for managing and allocating available patient safety resources. The success of a usability test often is measured by the positive change that occurs in the interface design and by the specific strategies implemented to improve the interface ease of use (e.g., training).

BCMA example

Findings from an analysis of the BCMA scenario-based usability testing data include the following:

- Practitioners did not complete tasks when automated actions occurred without their knowledge (e.g., medication orders dropped off the BCMA record automatically after a period of time, whether or not the medication had been administered).

- Data that appears on the display only when selected may be ignored or forgotten (e.g., medications that are visible only when certain filters are on may be missed without a visual cue to remind the user that the data has been hidden).
- Nonroutine activities that are part of the workflow process are not effectively supported by the system interface (e.g., users are required to leave the BCMA system and enter another to "undo" an action).

These results led to redesigns in the software so that (1) medications set to expire will not be removed from a patient's records without a nurse first being notified, (2) the default filter on the list of pending medications now displays all medications (i.e., one-time and interval dosages), and (3) a provision has been included in the BCMA graphical interface that allows nurses to note medications withheld or refused by the patient.

WMA example

In the WMA application, the usability tests identified the following shortcomings in the interface design:

- The placement of the virtual keyboard on the display screen obscured the nurse's view of crucial patient allergies data and had a significant impact on usability and safety.
- The small screen size eliminated key information from the display (e.g., patient identification information was displayed only after the patient's records had been loaded from the database).
- Like BCMA, the WMA interface should support report generation (e.g., the value of paper printouts used to supplement PDA interfaces should be considered since they support efficiently accessing and interpreting relationships from large collections of data).

These results led to significant improvements in the software interface: (1) two forms of positive patient identification—patient name and social security number—now are displayed at all times, once the patients record is loaded and confirmed; (2) the virtual keyboard no longer covers the lower portion of the allergies list; and (3) more interrelated information now is shown in parallel, and the process for retrieving information has been simplified.

Discussion

Scenario-driven usability tests are routinely created for innovations in software. Usability testing in the software industry involves a user performing a series of often unrelated single tasks (e.g., open a program, save a file), without performance pressure. Software used in health care can prevent patient injury or contribute to it, when usability testing is not designed to mitigate the effects of working conditions and decisionmaking complexity. Such testing might prevent accidents and provide "reasonable" safeguards that are truly effective (allergy

notification routinely is missed if not placed as a visible warning or on the multiple screens) and push design toward software that simplifies work, rather then adding new tasks.

The scenario-based usability testing we conducted for the BCMA and WMA systems in the Veterans Health Administration identified six negative, unintended side effects with the potential to create new paths to errors: (1) automated removal of medications in the BCMA system caused confusion; (2) poorly organized data screens resulted in missed medications; (3) users had to exit one system and log into another to complete documentation; (4) portions of the data display screens were blocked by the virtual keyboard; (5) key information from the BCMA system was not replicated on the WMA system; and (6) the WMA system would not support report printout generation, despite the nurses' need for it.

The scenario-based testing results revealed gaps between the conceptual model of the system and that of work practice. During the testing, when the nurses discovered medications were missing from the interface, confusion ensued. In most of the tests, however, the nurses realized that the medications automatically removed from the system should have been given and administered them eventually. The nurses said this type of design decision created a new potential path to missed medications.

The transition from the desktop BCMA interface to a hand-held WMA device required more design innovation than simply shrinking the larger laptop computer screen. Due to space limitations, the importance of the information and its organization on the screen takes on a new dimension as design trade-offs are made. And while the virtual keyboard is necessary for operating the tool, the information that it hides is also necessary for making decisions and providing complete care. Given that missing information is known to degrade performance with the desktop version of the system, the visual layout of the hand-held device and the methods for organizing the displayed information are even more critical. Identification information, for example, is key to patient safety and should be visible constantly.

The use of the WMA tool does not occur in a vacuum. In fact, because it is a mobile technology, it will be used in situations and circumstances where the desktop version is not practical. Similarly, work patterns developed through the use of the desktop version will be transferred to the WMA model. These patterns will be strengthened through the unique capabilities of the hand-held device. The scenario-based testing revealed that the work patterns did not change with the hand-held device, and the nurses still preferred to use the written reports that the desktop version can produce. Limitations related to the WMA created task complications, as users found themselves using the laptop computer for certain things and the hand-held unit for others.

Conclusion

Clinical information systems, by definition, are used to display volumes of information important to the care of patients. Design strategies are used to organize the interface in such a way that the most important information is available at a glance, without overwhelming the user. This is difficult to accomplish when there is a disconnect between the actual work practice and the system's design. Scenario-based testing can provide results that help designers to organize the interface in ways that support memory and assist in user recovery from errors. At the same time, however, this type of testing is not designed to determine whether or not the process itself is flawed.

Currently, our ability to predict the impacts of new technologies, prior to their introduction, is limited by our understanding of how technologies impact work practice. Scenario-based usability testing results will feed back into a research base, providing further insights into how the dimensions of the technology impact the work it exists to support. Increased understanding of these dimensions will enable us to make design changes prior to implementation that will improve the technology's usefulness and reduce unintended side effects at a point in the design process when changes are much less expensive and risky to make.

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